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09/982,093	10/19/2001	S. Rao Cherukuri	69710.000005	6757

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/982,093	CHERUKURI, S. RAO	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 27-39* is/are pending in the application.

4a) Of the above claim(s) *36 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 27-35, 37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks, all filed 2/19/09.

Claims 25, 27-35 are amended. New claims 36-39 are added. Claims 25 and 27-39 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/19/2008 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25, 27-29, 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Claim 25 and new claim 35 give the diameter and length of the caplet as ranging from about 1 millimeter to about 3 millimeter. The specification at the abstract and at paragraphs [0019], [0023] and [0074] of the published application and original claim 1 disclose and recite that the diameter of the caplet is from about 1 millimeter to about 7 millimeter. Paragraphs [0098], [0101], [0104] and [0107] of the published application disclose caplets having specific diameter of 3 millimeter and 1.3 millimeter. The specification as originally filed does not envision diameters in the range of about 1 millimeter to about 3 millimeters. This is new matter.

The above rejection may be overcome by removing the new matter from the claims.

Response to Arguments

5. Applicant's arguments filed 2/19/09 have been fully considered but they are not persuasive.

6. Applicant argues that the claimed diameter and length of the caplet in the range of from 1 millimeter to about 3 millimeter is sufficiently supported by the disclosure of 1-7 mm and that the situation is similar to *in re Wertheim* at 541 F.2d 257 (CCPA 1976) and also that 1 millimeter to about 3 millimeter does not have to be disclosed *ipsis verbis* because the disclosed range of 1 millimeter to about 7 millimeter and a specific disclosure for a diameter and length of 3 millimeter supports the claimed range.

7. The examiner disagrees. A range of 1 millimeter to about 3 millimeter is what it is since the upper limit of about 3 is much less than 4.5, say. Contrary to applicant's assertion, the now claimed range is not envisioned by the originally filed application. While the 3 millimeter specie may be part of the disclosed genus of 1-7 and the claimed genus of 1-3, the genus range of 1-7 does not provide support for the genus range of 1-3 or the species of 1-3 mm does not support the full scope of the genus 1-7 mm. Therefore, the diameter and length in the ranges recited in claims 25 and 35 are not envisioned at the time the original specification was filed.

8. Claims 25, 27-35, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter.

9. The specification as originally filed does not envision “plurality of encapsulated products,” and “plurality of encapsulated caplets.” "One or more encapsulated products” as disclosed in the instant specification at page 25, lines 8-12 do not represent plurality of encapsulated products where each encapsulated product comprises venlafaxine, compressible material, lubricating agent. The section of the specification referenced by applicant has to do with encapsulating one or more products, where the product is one or more of products included in the chewing gum and not that many capsules of venlafaxine comprising venlafaxine, compressible material and lubricant are included into the chewing gum.

10. The as filed specification does not envision a composition that comprises granules, with each granule comprising venlafaxine, compressible material and lubricant.

11. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. New claim 37 depends on canceled claim 1 and as such the scope of the claim is not clear.

13. Claims 25, 27-35, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 25 recites a composition that comprises plurality of encapsulated products with each encapsulated product comprising venlafaxine, compressible material and lubricant, and each encapsulated product is then tableted using a tableting machine. Claim 25 is ambiguous and is thus indefinite. Claim 35 is also unclear.

15. The claims are examined as tablets or caplets comprising granules or particles of comprising venlafaxine, compressible material and lubricants.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 25, 27-32, 34 and 35 and new claim 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al. (US 6,197,828) in view of Doyon et al. (US 5,283,065) or Nicklasson (US 5,431,922) or Roser et al. (US 5,762,961).

18. Amended claim 25 and 35 recite the process of making the dosage form. But, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps and "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

19. Jerussi describes pharmaceutical dosages in the form of tablets, caplets, troches, lozenges (column 15, line 34; column 16, line 14); the dosage form comprises pharmaceutical carrier/binder/filler in pharmaceutically compatible and pharmaceutically acceptable amounts and active ingredient (column 15, lines 38-43; column 17, lines 14-22); the binder is "corn starch, potato starch, or other starches, gelatin, natural and synthetic gums such as acacia, sodium alginate, alginic acid, other alginates, powdered tragacanth, guar gum, cellulose and its derivatives (e.g., ethyl cellulose, cellulose acetate, carboxymethyl cellulose calcium, sodium carboxymethyl cellulose), polyvinyl pyrrolidone, methyl cellulose, pre-gelatinized starch, hydroxypropyl methyl cellulose,... microcrystalline cellulose, and mixtures thereof," (column 17, line 65 to column 18, line 7); disintegrants are "agar-agar, alginic acid, calcium carbonate, microcrystalline cellulose, croscarmellose sodium, crospovidone, polacrilin potassium, sodium

starch glycolate, potato or tapioca starch, other starches, pre-gelatinized starch, other starches, clays, other algins, other celluloses, gums or mixtures thereof" (column 18, lines 44-50); lubricants are "calcium stearate, magnesium stearate, mineral oil, light mineral oil, glycerin, sorbitol, mannitol, polyethylene glycol, other glycols, stearic acid, sodium lauryl sulfate, talc, hydrogenated vegetable oil (e.g., peanut oil, cottonseed oil, sunflower oil, sesame oil, olive oil, corn oil, and soybean oil), zinc stearate, ethyl oleate, ethyl laureate, agar, or mixtures thereof" (column 18, lines 51-59); the active ingredient is pharmaceutically venlafaxine or venlafaxine derivative (column 2, lines 43-47) or pharmaceutically acceptable salt (column 3, line 14), and included in the pharmaceutical salt is the hydrochloride salt (column 4, line 43). The hydrochloride salt of venlafaxine meets the venlafaxine HCl of claim 25; the lubricating agents meet the claim 25 c) and 35 b); the calcium carbonate meets claim 25 b) and claim 34 and 36 a); the polyvinylpyrrolidone meets the binder of claim 25 d; the microcrystalline cellulose meets claim 29. For claims 31 and 32, the lubricating agent when applied would inherent form a film and because the lubricating agents of the prior art are the same as those recited in claim 25 c), the lubricating agents of the prior art are hydrophobic. While column 19, lines 1-7 disclosed mg amount of the active agent, Jerussi broadly teaches the above described dosage form; and for claims 27 and 28, the artisan is capable of designing caplet or tablet dosage form that comprises desired amounts of active agents and carrier/filler/binder for delivery and treatment of the various disorders disclosed (see column 4, line 50 to column 5, line 60). Jerussi is silent on the dimensions of the caplet. However, it would have been obvious to prepare the caplet having desired dimensions of length and diameter because the technique of tableting using commercially available tablet press is well recognized as part of the ordinary capabilities of the skilled artisan so that it would have been obvious to prepare caplets having desired dimensions of length and

diameter. In the absence of factual evidence, caplet having the recited dimensions of length and diameter is not inventive over the caplet of the prior art that is silent on the dimensions of the caplet keeping in mind that caplets inherently have length and diameter. The cellulose of Jerussi meets the requirements for the carbohydrate of claims 25 and 38.

20. Jerussi does not teach particles or granules that are incorporated into caplet or tablet or capsule. But, sustained release dosage forms are known to be formulated as multi-particulate forms incorporated into caplets or compressed into tablet forms. For example, granules comprising active agents and excipients are compressed into tablets to present rapidly soluble dosage forms (according to column 5, lines 50-55 of US 5,762,961) and one class of active agents so formulated is an anti-depressant (column 7, line 59 of the US 5,762,961). The other example is the compression of spherical granules into a controlled released tablet form and in case antidepressant is one of the classes of the drugs so formulated to provide the controlled release dosage form (see the entire document of US 5,283,065 with emphasis in column 5, lines 27-40, 44-49; column 6, lines 31-36, 60). Another example is the filling of hard capsule with microcapsules or coated pellets of active agent or gentle compression of microcapsules or coated pellets of active agents into a tablet (see the entire document of US 5,432,922 with emphasis on column 5, lines 21, 26; column 7, lines 3-43).

21. Therefore, taking the teachings of Jerussi in combination with Roser (US 5,762,961) or Doyon (US 5,283,065) or Nicklasson (US 5,431,922), one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that formulating the venlafaxine antidepressant in particulate form would provide controlled release of the drug.

22. Claims 25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al. (US 6,197,828) in view of Doyon et al. (US 5,283,065) or Nicklasson (US 5431,922) or

Roser et al. (US 5762961) and further in view of Appel et al. (US 2002/0015731) or Chungi et al. (US 6,306,436).

23. Jerussi in view of in view of Doyon or Nicklasson or Roser has been described above to render claim 25 obvious by teaching venlafaxine containing dosage in the form of caplet and comprising venlafaxine hydrochloride salt, binders, lubricant, disintegrants and fillers as microparticulate forms for compression into tablet or incorporation into capsule. While the composition of Jerussi contains polyvinylpyrrolidone, the composition of Jerussi does not contain polyvinyl acetate.

But formulations containing venlafaxine are known to contain polyvinyl acetate. For example, Appel discloses compositions containing venlafaxine and polyvinyl acetate (paragraphs [0036] and [0038]. Chungi also teaches compositions that contains venlafaxine and mixture of polyvinyl acetate and polyvinylpyrrolidone and in this case, the mixed carrier comprising mixture of polyvinyl acetate and polyvinylpyrrolidone is reported to stabilize the composition (column 5, lines 58-60; column 7, line 42, claims 14-16). Thus, Appel and Chungi are relied upon for teaching that polyvinyl acetate can be included with Venlafaxine. Therefore, taking the teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that including polyvinyl acetate in the composition of Jerussi would lead to the desired dosage form and also assist in stabilizing the composition.

Response to Arguments

24. Applicant's arguments filed 2/19/09 have been fully considered but they are not persuasive.

25. Applicant argues for the withdrawal of the rejections over Jerussi and Jerussi in view of Appel or Chungi because neither Jerussi nor Jerussi in combination with Appel or Chungi teaches granules that are mixed with lubricant and subsequent compression into tablet. Applicant's arguments as it relates to the present invention are not persuasive. While the examiner agrees with the applicant that Jerussi does not teach granules, it is known in the art that granules provide controlled release or sustained release. The present rejections have considered the amendment and the secondary references have been applied to show that dosage forms formulated as granules provide sustained/controlled release.

26. Applicant has also indicated that it took applicant a fair amount of time to modify Jerussi and was unable to form a tablet. However, it is also respectfully brought to applicant's attention that the declaration filed 3/31/2006 was fully addressed in the office action of 6/19/2006. It is also noted that the claims have been amended so many times that when the claims mirror previously rejected claims, then prior art that may have been previously dropped is used.

27. Furthermore, the examiner notes that the dimensions of the caplet recited in the generic claim are a range of 1-3 mm. On 1/14/05 applicant described of compositions (12 and 13 of the remarks filed 1/14/05) and indicated that a dissolution profile in 0.1N HCl of 11 mm tablet and 3 mm caplet was presented a an attached chart. But Jerussi teaches caplet formulation and it is unclear how comparison of dissolution profile between 11 mm tablet, 3 mm caplet and dimensionless capsule is evidence that a caplet having diameter and length in the range of 1-3 mm (7 mm) is unexpected and superior to another caplet with a realization that caplets by design have dimension, even if the prior art is silent on the dimensions; and that the artisan has the technical knowledge to determine those dimensions.

28. In the current remarks of 5/1/08 at page 7, the applicant prepares three products, i) capsule, ii) 11 mm tablet and iii) 3 mm caplet; tests the dissolution profile in 0.1 N HCl and shows dissolution profile of the three in Exhibit A. The examiner disagrees that the dissolution profile presented in Exhibit A and the products tested as described on page 7 of the present remarks filed 5/1/08 makes the instant composition patentable over the composition of the prior art. Firstly, the composition on page 7 of the present remarks filed 5/1/08 is not a representation of the claimed product/composition in claim 25 since no amounts of the venlafaxine, lubricating agent and binder is recited. Secondly, Jerussi contemplates and teaches caplet dosage form. Thirdly, the dissolution profile compares different sizes of tablets and caplets instead of comparing caplets of different dimensions. Fourthly, the generic claim recites the dimensions in a range of 1-3, and the data does not show what happens at dimensions outside the recited range using caplets of varying dimensions. Therefore, the data presented on 5/1/08 failed to provide unexpected results over the caplet dosage form of Jerussi that contains venlafaxine, lubricant, binders and fillers.

Election/Restrictions

29. Newly submitted claims 36 and 39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The composition that has been previously examined can be prepared by methods other than the method of new claims 36 and 39.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36 and 39 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Furthermore, MPEP 819 [R-3] states that "applicant cannot as a matter of right file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined." In this case the method claims 36 and 39 presented with the filing of the RCE is restricted out because the prosecution of this application has not examined the method claims before. See also MPEP 821.03 [R-3].

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618